

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1, 2, 4-13, 16, 17 and 20-31 were pending in this application when last examined.

Claims 1, 2, 4-13, 27, 28 and 30 were examined on the merits and stand rejected.

Claims 16, 17, 20-26, 29 and 31 were withdrawn as non-elected subject matter.

Applicants' reserve the right to file a continuation or divisional application on any non-elected subject matter. Applicants further request that if the elected species is found allowable then the search will be extended to the other species of the claimed invention.

Claims 1 and 27 are amended to clarify the claimed invention.

No new matter has been added.

I. CLAIM OBJECTIONS

In item 4 on page 2 of the Office Action, claim 27 was objected to. This objection is overcome, as applied to the amended claim, for reasons which are self-evident.

II. OBVIOUSNESS REJECTION

In item 5 on pages 3-6 of the Office Action, claims 1, 2, 4-13, 27, 28 and 30 were rejected under 35 U.S.C. § 103(a) as obvious over Chen in view of Rava et al., Klessing et al., Poethke et al., Hu and Sanderson et al. Applicants respectfully traverse this rejection.

The Examiner indicates that Chen teaches a method of preparing a plurality of monoclonal antibodies comprising immunizing an animal with homogenized tissue and identifying the monoclonal antibodies using a chip displaying antibodies. The Examiner further contends that Rava and Poethke disclose that monoclonal antibodies can be identified using a chip displaying antigens or a plate coated with antigens. Finally, the Examiner contends that Klessing, Poethke and Hu teach preparation of a plurality of monoclonal antibodies by immunizing an animal with purified antigens, and further isolate and identify the antibodies that bind to the purified antigens. Thus the use of purified proteins to make a plurality of monoclonal antibodies and further isolate and identify the antibodies using an array displaying the purified

antigens were clearly in the purview of those of ordinary skill in the art and was within the knowledge of those in the art at the time the invention was made.

Applicants respectfully disagree with the Examiner's position.

The claimed invention is directed towards a high throughput method for providing a plurality of monoclonal antibodies each of which binds to a different candidate antigen. The claimed method is directed towards (1) introducing a plurality of purified candidate antigens into an animal or animals; (2) recovering antibody producing cells from said animal or animals, rendering the cells into single cell suspensions and generating immortalized cell lines from said single cell suspensions; (3) screening the supernatant of said immortalized cell lines against a protein chip on which purified candidate antigens are displayed; (4) and selecting monoclonal antibodies that bind to said candidate antigens.

In order to arrive at the claimed invention from the teachings cited by the Examiner, a person of skill in the art would have to substitute the homogenized cell extract of Chen with purified candidate antigens. A person of skill in the art would further have to substitute the monoclonal antibodies of Chen on the chip with the purified antigens of the claimed invention. Finally, a person of skill in the art would have to replace the detection method of Chen, which comprises adding an antigen and a polyclonal antibody to the chip of Chen, with the streamline process of merely adding supernatant of the immortalized cell lines of the claimed invention.

The Examiner indicates that such modifications are taught by the secondary references. However, Applicants note that in the recent Supreme Court decision in KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727 (U.S. 2007), the Supreme Court stresses that some rationale must be articulated for combining references. Applicants respectfully suggest that the Examiner has failed to provide such rationale and therefore has failed to establish a case of obviousness.

In particular, turning to Rava, such reference teaches a large genus of biological arrays containing various probes among one of which is a peptide. Without the guidance given in the application (which is an improper application of hindsight) a person of skill in the art has no rationale for choosing protein chips with purified antigens on their surface.

Further, neither Rava or Klessing, Poethke and Hu teach direct detection of antibodies bound to protein chips displaying antigens. The Examiner has failed to provide a rationale or even prior art for substituting the monoclonal antibody-antigen-polyclonal antibody detection method of Chen with the direct detection of antibodies of the claimed invention.

Finally, the Examiner has failed to present a rationale indicating why a person of skill in the art would substitute the homogenized tissue of Chen with purified antigens. Klessing, Poethke and Hu merely suggest immunizing animals with a plurality of antigens. However, such do not provide a rationale for substituting such in the teachings of Chen.

Thus, Applicants note that to arrive at the claimed invention a person of skill in the art must make numerous and significant modifications to the methods of Chen. However, the Examiner has failed to provide a rationale for a person of skill in the art making such modifications. As noted in MPEP 2143(A) “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” (Citing KSR). Applicants note that due to the large number of modifications made to Chen to arrive at the claimed invention it is important to identify a reason to make such modifications. However, the only apparent reasons for making such modifications seemed to be based on the realization by the Applicants that the claimed method has enormous advantages.

The Examiner is further directed towards *In Re Dembiczak et al.*, 175 F.3d 994. In this case, the Federal Circuit noted that “...the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine the prior art references” in *re Dembiczak et al.*, 175 F.3d. at 999. The Examiner is further directed to *Ruiz*, 234 F.3d 445 at 665, which indicates that “combining prior art references without evidence of such a suggestion, teaching or motivation simply takes the inventors disclosure as a blueprint for piecing together the prior art to defeat patentability [which is] the essence of hindsight”.

Applicants respectfully suggest that the motivation or rationale for combining these references to arrive at the claimed invention is not found in the references cited by the Examiner but is only found in the enormous advantages given by Applicants in the specification. Therefore, Applicants respectfully suggest that this rejection is untenable as it is improperly based on hindsight. Applicants may have combined elements previously known in the prior art, but such was only due to their realization that such combination would result in enormous advantages for high-throughput production and screening of monoclonal antibodies against large numbers of antigens simultaneously.

Furthermore, attached herewith is a Declaration by one of the inventors who is a person of skill in the art of the claimed invention. The Declarant also notes that in order to arrive at the claimed inventions from the teachings cited in the Office Action, a person of skill in the art would have to substitute the homogenized cell extract of Chen with purified candida antigens, substitute the monoclonal antibodies of Chen on the chip with the purified antigens in the claimed invention and replace the detection method of Chen with a streamline process of merely adding supernatant of the immortalized cell lines of the claimed invention. The Declarant's expert opinion and belief is that without the insight of the inventors, a person of skill in the art would not choose to display purified antigens on the surface of a chip. Further, Declarant is of the expert opinion and belief that a skilled artisan would not be motivated to use a plurality of purified antigens in the method of Chen unless such artisan realized the advantages discovered by the inventors. Thus, the Declarant is of the expert opinion and belief that a person of skill in the art would not be motivated or have a rationale based on the cited references to arrive at the claimed invention from the teachings in the cited references. Further, because of the enormous advantages conferred in the claimed invention, it is the Declarant's expert opinion and belief that if such method was obvious based on the cited references it would have been obtained at an earlier date.

Applicants respectfully note that under MPEP § 716.01 (a), Declarations, when timely presented, must be considered by the Examiner.

Applicants respectfully suggest therefore that the claimed invention is not rendered obvious by the cited art and this rejection is untenable as improper hindsight and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Alan M. SAWYER et al.

By /William R. Schmidt, II/

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